ORIGINAL ARTICLE

A comparative study of the different diagnostic criteria of gestational diabetes mellitus and its incidence

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ABSTRACT

BACKGROUND

High prevalence of diabetes and genetic predisposition to metabolic syndrome among Indians places Indian women at risk to develop gestational diabetes mellitus (GDM) and its complications. Literature defines multiple criteria for GDM. This prospective study compares available diagnostic criteria for GDM in Indian women and their correlation with perinatal morbidity.

METHOD

Nine hundred and forty-eight consecutive voluntary nondiabetic pregnant women were recruited for the study. Seven hundred and twenty-three of these (mean age 23.45 years; 75.7% < 25 years) who reported for the follow-up were screened for GDM at 24–28 weeks gestation by American College of Obstetrics and Gynaecology (ACOG) guidelines and World Health Organization (WHO) criteria. Glycated haemoglobin (HbA_{1c}) and fasting and two-hours postglucose plasma insulin levels were also analysed. Pregnancy outcome was known for 291 of these. Concordance of risk factors and perinatal complications was analysed with respect to GDM.

RESULTS

Prevalence of GDM at 24–28 weeks gestation was found to be 4.8% by WHO criteria, 6.36% by Carpenter and Coustan's criteria, and 3.5% by O'Sullivan's criteria. Prevalence was marginally higher in women of higher age, having past history of abortion or family history of diabetes mellitus (DM) ($P > 0.05$). None of these women had $HbA_{1c} > 6\%$. Relative risk of abnormal delivery (pregnancy outcome) was 1.93, 1.39, and 1.17 in women with GDM by O'Sullivan's, WHO, and Carpenter's criteria, respectively ($P > 0.05$). Abnormal deliveries were marginally higher in women with high postglucose load insulin levels. Mean weight of the newborns was essentially the same in GDM and nonGDM women by any of the criteria. One-hour and two-hours postglucose values were more sensitive in diagnosing GDM by O'Sullivan's criteria while fasting plasma glucose value had the poorest specificity with 2.5% of nonGDM women having values above the cut-off. Modifications of these criteria did not improve their predictive value for abnormal delivery over that of O'Sullivan's criteria.

CONCLUSION

Prevalence of GDM and abnormal delivery in women < 35 years of age is low. Therefore, global screening for GDM may not be very useful in women < 25 years of age unless family history of DM or past history of abortion is present. Existing evidence is inadequate to justify the switchover from O'Sullivan's criteria for diagnosis of GDM.

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INTRODUCTION

India is the country with the largest number of people with diabetes, with an estimated figure of 57 million by the year 2025.[1] Recent reports suggest dyslipidaemia, hypertension, and insulin resistance is more common in Asian Indian women.[2] High prevalence of diabetes and genetic predisposition to metabolic syndrome among Indians place Indian women at risk to develop gestational diabetes mellitus (GDM) and its complications.[3] Therefore adult females, who have inherited genetic predisposition to type 2 DM, would be at higher risk of developing GDM during pregnancy.

For the mother with GDM there is a higher risk of hypertension, pre-eclampsia, urinary tract infection, caesarean section, and future diabetes. In the foetus or neonate, the disorder is associated with higher rates of perinatal mortality, macrosomia, neural tube defects, neonatal hypoglycaemia, hypocalcaemia, hypomagnesaemia, hyperbilirubinaemia, birth trauma, pre-maturity syndromes, and subsequent childhood and adolescent obesity.[4,5] Available data do not identify a threshold of maternal glycaemia at which such risk begins or increases rapidly. The criteria currently recommended by the American Diabetes Association[6] are based on O'Sullivan's criteria. Carpenter and Coustan recommended stricter criteria[7] after 100 g oral glucose load and the most recent American College of Obstetrics and Gynaecology (ACOG) practice bulletin supports the use of either criterion.[8] In addition, criteria for interpretation of a 75 g two-hours oral glucose tolerance

test (OGTT) was acknowledged by World Health Organization (WHO). There has been no study comparing these criteria.

Indians are ethnically different with an established predisposition to diabetes and metabolic syndrome. Also, in India a significantly higher number of individuals have abnormal two-hours postglucose levels as compared to fasting plasma glucose values.[9] Therefore, this prospective study was undertaken to evaluate the incidence of GDM in Indian women by different diagnostic criteria and to study their correlation with perinatal morbidity.

MATERIALS AND METHOD

Nine hundred and fifty-three booked antenatal cases attending the Obstetrics and Gynaecology outpatient department (OPD) were enrolled. Five cases with history of diabetes before pregnancy or presence of obvious diabetes at registration were excluded from the study, these were diagnosed with standard OGTT (75 g glucose load), as recommended by WHO. Out of these 948 cases only 723 cases reported for follow-up and were screened at random by one step O'Sullivan's criteria (ACOG guidelines) and WHO criteria, sequentially, between 24 weeks and 28 weeks of gestation. The cut-off values for venous plasma glucose after 100 g glucose load, for diagnosis of GDM by O'Sullivan's, Carpenter and Coustan's, and after 75 g glucose load by WHO criteria are as follows:

Sample	Venous plasma glucose (mg/dL)		
	O'Sullivan's criteria* 100 g OGTT	Carpenter and Coustan's criteria* 100 g OGTT	WHO 75 g OGTT
Fasting	105	95	≥126 and/or
1 hr	190	180	–
2 hr	165	155	≥140
3 hr	145	140	–

OGTT: oral glucose tolerance test, WHO: World Health Organization.
*Gestational diabetes is diagnosed if two or more of the values are met or exceeded.

We also analysed our results with a 'Modified Criteria', the cut-off values for this being, IFG and/or DM by American Diabetes Association (ADA). A criteria i.e. fasting plasma glucose of ≥100 mg/dL and/or oral 75 g two-hours postglucose load plasma glucose value of ≥140 mg/dL.

Risk factors such as age, pregnancy weight, family history of diabetes in a first degree relatives, eclampsia, previous large baby, previous congenital malformations, and previous perinatal loss were noted. In spite of the best efforts, pregnancy outcome and perinatal complications could be followed up in only 340 cases who delivered at Command Hospital. Out of these only 291 under took O'Sullivan's and WHO recommended OGTT at 24–28 weeks. Remaining cases were lost to follow-up due to either various customs prevailing in Indian societies or due to lack of awareness among the study group regarding the importance of undergoing complete investigation and hospital delivery.

These patients were followed up for complications in mother like hypertension, pre-eclampsia, urinary tract infections, caesarean section, and in foetus or neonate for hydramnios, perinatal mortality, macrosomia, neural tube defects, birth trauma and infant birth weight. Also fasting and two-hours postglucose serum insulin was studied in the antenatal cases.

The cases detected to have GDM with ACOG criteria were clinically managed. The results of WHO criteria were compared with ACOG guidelines and cases not found to be positive by ACOG guidelines but positive by WHO criteria, were followed up for occurrence of various complications of GDM. The history of abortion, family history of diabetes and other risk factors were also compared with results of both criteria.

Glucose estimation was done by glucose oxidase-peroxidase (GOD-POD) method and insulin estimation by immunoradiometric assay. Glycated haemoglobin (HbA_{1c}) was estimated using high-performance liquid chromatography (HPLC) kit procured from Recipe Chemicals and Instruments GmbH, Munich, Germany.

Pregnancy outcome could be recorded only if the delivery was conducted in the Command Hospital (SC). In addition to mode of delivery, weight, and sex of the infant and any perinatal complication if present were recorded. The outcome has been grouped into four categories as (1) normal delivery, (2) post-lower segment caesarean section (LSCS) caesarean delivery, (3) emergency caesarean delivery, and (4) others, as comprising of preterm, premature rupture of membranes (PROM), intra-uterine growth restriction (IUGR), still birth, etc.

The association between GDM by various criteria and pregnancy outcome into above four categories were studied to find any correlation. For the statistical analysis three groups other than normal delivery were clubbed together as abnormal delivery, the number in each of the three groups not being adequate for statistical analysis. The statistical analysis was carried out using Epi Info Programme from Centres for Disease Control and Prevention (CDC), USA.

RESULTS

Nine hundred and fifty-three booked antenatal cases were enrolled. All women were screened for pre-existing diabetes in the first trimester by routine fasting and postprandial glucose estimation and five women were found to be positive for presence of diabetes. The remaining nondiabetic 948 antenatal cases were followed up. Past history of abortion, family history of diabetes in first degree relatives, obesity, and age of these patients were noted.

Most of the women (99.7%) in our study were in the age group of <35 years and >3/4th (75.7%) were of ≤25 years of age. The highest number of GDM (5.74%) by WHO criteria was present in age group of 25–35 years. The incidence of GDM was 4.8% and 3.5% by WHO and O'Sullivan's criteria, respectively.

Past history of abortion and family history of DM was found in 23.7% and 17.9% of the females who were investigated at

Table 1 Association between past history of abortion and family history of diabetes in first degree relatives with gestational diabetes mellitus by O'Sullivan's criteria and World Health Organization criteria at 24–28 weeks.

GDM criteria	Past history of abortion*		Family history of DM	
	Positive	Negative	Positive	Negative
	$n = 171$ (23.7%)	$n = 552$ (76.3%)	$n = 57$ (17.9%)	$n = 666$ (92.1%)
WHO +ve	9 (25.7%)	26 (74.3%)	6 (17.1%)	29 (82.9%)
WHO −ve	162 (23.5%)	526 (76.5%)	51 (7.4%)	637 (92.6%)
O'Sullivan's +ve*	10 (40%)	15 (60%)	3 (12%)	22 (88%)
O'Sullivan's −ve	161 (23.1%)	537 (76.9%)	54 (7.7%)	644 (92.3%)

DM: diabetes mellitus, GDM: gestational diabetes mellitus, WHO: World Health Organization.
*$\chi^2 = 3.83$; $P = 0.05$.

Table 2 Distribution of glycated haemoglobin values during 24–28 weeks of pregnancy and presence of gestational diabetes mellitus by O'Sullivan's criteria.

HbA_{1c} (%)	Normal HPLC profile	
Range (mean$\pm$SD)	2.4–5.9 (4.46$\pm$0.61)	
	GDM −ve	GDM +ve
≤ 3.5	18	1
$> 3.5–4.5$	99	2
$> 4.5–6.0$	114	2
Total	231	5

GDM: gestational diabetes mellitus, HPLC: high-performance liquid chromatography, HbA_{1c}: haemoglobulin A_{1c}, SD: standard deviation.

24–28 weeks for GDM. We observed that those with past history of abortion or family history of DM had higher percentage of GDM by either criterion, although the differences were not statistically significant except for the past history of abortion and presence of GDM by O'Sullivan's criteria (Table 1).

We studied HbA_{1c} and GDM by O'Sullivan's criteria in 260 of pregnant females at 24–28 weeks. One case was excluded who had diabetes at initial registration with HbA_{1c} of 9.3%. None of the remaining individuals had $HbA_{1c} > 6.0$% even if they tested positive for GDM by O'Sullivan's criteria (Table 2). The samples giving additional peaks ($n = 23$) during HPLC separation were identified to have the presence of haemoglobin S (HbS), HbE, HbD or HbA_2 or an abnormal peak which could not be identified. All of these cases were referred as having abnormal HPLC profile. The group with abnormal HPLC profile for haemoglobin had significantly lower mean HbA_{1c} value (2.85%) from individuals with normal profile (4.46%). This could be due to the fact that red blood cells with abnormal haemoglobin have shorter half-life and rapid turnover resulting in lesser degree of glycation.

The association between pregnancy outcome and GDM by various criteria is summarised in Table 3. Highest relative risk (RR = 1.93) of abnormal delivery has been found in patients positive for GDM by O'Sullivan's criteria. However, the relative risk among different criteria has not been found to be significantly different statistically.

The insulin levels have been grouped into tertiles and the association of pregnancy outcome with different insulin levels is illustrated in Table 4. There is no statistically significant difference in abnormal outcome and plasma insulin levels in fasting and postglucose load samples. However, the higher percentage of women 100 g two-hours postglucose load plasma insulin level have higher incidence of abnormal deliveries in comparison to the first tertile group of insulin level (Table 5).

Fasting and Postglucose Load Plasma Glucose Levels

The minimum, maximum, and mean (SD) values of fasting and postglucose load plasma glucose values by different criteria were analysed and are presented in Table 5. Among the GDM positive cases 48, 84, 80, and 52% had venous plasma glucose values higher than cut-off with O'Sullivan's criteria at fasting, one-hour, two-hours, and three-hours, respectively. Additionally, fasting values had poorest specificity with 2.5% of nonGDM women having values above the cut-off. Postglucose, 75 g two-hours criteria of WHO could detect only 20% cases of GDM by O'Sullivan's criteria while 0.4% and 4.0% of GDM negative cases were identified as GDM based on fasting and two-hours WHO criteria, respectively. Therefore, WHO cut-off for GDM is not adequate to detect the 100 g postglucose load hyperglycaemia which occurs more frequently in one-hour and two-hours samples in GDM positive cases. Most of the GDM positive cases (68%) by O'Sullivan's criteria had plasma glucose values above cut-off level in one-hour and two-hours plasma samples.

The weights of the new born were in the range of 1.302–4.003 Kg with 2.654 (0.413) Kg as mean (SD). The new born weights were not different in GDM positive and negative mothers by any of the criteria. Moreover, only one new born was classified to be macrosomic with birth weight of 4.003 Kg from a nonGDM mother.

The Prevalence of Gestational Diabetes Mellitus by Different Criteria and Relationship to Pregnancy Outcome

Prevalence of GDM diagnosed between 24 weeks and 28 weeks by Carpenter and Coustan's, WHO, and O'Sullivan's criteria are 6.36, 4.8, and 3.45%, respectively. Prevalence was obviously lowest when diagnosed by O'Sullivan's criteria, as it has higher fasting, one-hour, two-hours, and three-hours, cut-off than the

Table 3 Association between pregnancy outcome and gestational diabetes mellitus at 24–28 week by O'Sullivan's, World Health Organization, and Carpenter and Coustan's criteria.

Delivery	O'Sullivan		WHO		Carpenter and Coustan	
	Positive	Negative	Positive	Negative	Positive	Negative
Abnormal	3	74	4	73	4	73
Normal	3	211	8	206	9	205
Total	6	285	12	279	13	278
Relative risk (95% CI)	1.93 (0.84–4.39)		1.39 (0.43–4.48)		1.17 (0.51–2.71)	

WHO: World Health Organization.

Table 4 Association of pregnancy outcome with fasting and two-hours postglucose load (100 g) insulin levels at 24–28 weeks.

Insulin Tertile	Fasting Delivery n (%)		Two-hours postglucose load Delivery n (%)	
	Abnormal	Normal	Abnormal	Normal
1st	16 (32.3)	32 (66.7)	09 (19.1)	38 (80.9)
2nd	13 (29.5)	31 (70.5)	19 (41.2)	27 (58.7)
3rd	15 (31.2)	33 (68.8)	16 (34.0)	31 (66.0)
Total	44 (31.4)	96 (68.6)	44 (31.5)	96 (68.5)

Carpenter and Coustan's criteria. Moreover these are based on at least two cut-off values, rather than one value only as in WHO criteria. The number of different criteria being positive in a particular case and their association with pregnancy outcome is given in Table 6. However, 92.1% did not test positive by any of the three criteria.

We compared diagnostic utility of various criteria in 723 cases who have undergone all the investigations. The comparative figures are given in Table 7. The Carpenter and Coustan have higher sensitivity, specificity, positive predictive values (PPV), and negative predictive values (NPV) than WHO criteria. We also tried to analyse diagnostic utility of a 'Modified Criteria' with fasting venous plasma glucose of ≥100 mg/dL (IFG criteria) which is close to 105 mg/dL of O'Sullivan's and 95 mg/dL of Carpenter and Coustan's fasting cut-off criteria or 75 g two-hours postglucose load venous plasma glucose of ≥140 mg/dL (impaired glucose tolerance (IGT) or DM criteria) of ADA/WHO. The test has better sensitivity, PPV, and NPV than WHO criteria. Carpenter's criteria have cut-off values lower than O'Sullivan's criteria for a positive GDM test. Therefore, those found to be positive by Carpenter's criteria will be obviously positive by O'Sullivan's criteria and hence it has sensitivity of 1.0 and a specificity of 0.97 while the sensitivity is greatly lost in WHO criteria as the fasting plasma glucose cut-off is relatively high at ≥126 mg/dL. When we lowered the fasting plasma glucose cut-off to IFG (≥100 mg/dL) as in 'Modified Criteria' the sensitivity was greatly improved.

We tried to analyse the pregnancy outcome with O'Sullivan's, Carpenter and Coustan's, and WHO criteria. The pregnancy outcomes as abnormal delivery have been compared in Table 8, which includes previous LSCS, emergency LSCS and other deliveries (preterm, IUGR, still birth, etc.). It is obvious from

Tables 7 and 8 that while 'Modified Criteria' has higher incidence of GDM it does not have higher percentage of abnormal deliveries than O'Sullivan's criteria.

DISCUSSION

We know that the risk factors for GDM are strong family history of diabetes, age >35 years, past history of abortions and marked obesity. Out of a total of 723 followed up cases at 24–28 weeks, 35 were found to be GDM by WHO criteria and 25 by O'Sullivan's criteria. Those with past history of abortions and family history of DM in first degree relatives had higher incidence of GDM (Table 1). However, it was not significant; the P value for these observations was >0.05.

In a large retrospective cohort study in Canada, Xiong et al evaluated 111,563 pregnancies and detected 2.5% prevalence of GDM. The risk factors identified were age >35 years, obesity, history of prior caesarean section. In our study, the mean age of the present study group was 23.45 years.[9] There were only two patients with age ≥35 years out of 723 cases and these were not positive for GDM by WHO or O'Sullivan's criteria. However, the number is very small for the finding to be of any statistical significance. The percentage of individuals with GDM by O'Sullivan's criteria were 3.1% and 4.6%, in age group up to 25 years of age and >25–35 years of age, respectively. The incidence of GDM has been reported to vary widely in Indian population from <1% to 16%.[10-12] Ramachandran et al reported the incidence of GDM as 0.56% in Chennai population by O'Sullivan's criteria[11] while Krishnaveni et al has found the incidence of 6.5% by Carpenter and Coustan's criteria in south Indian women.[12] Seshiah et al reported the higher GDM incidence of 16%.[13] Diabetes in pregnancy study group India (DIPSI) has proposed an additional category of Gestational Glucose Intolerance (GGI) as having 75 g two-hours postglucose load venous plasma glucose of ≥120 and <140 mg/dL, but this does not have much relevance to the present study.[14]

Overall prevalence of GDM between 24 weeks and 28 weeks by WHO and O'Sullivan's criteria was detected to be higher by WHO criteria than by O'Sullivan's criteria (i.e. 4.8 as compared to 3.5%) (Table 1). However, there is poor concordance between the two tests. In GDM one of the maternal complications is emergency caesarean delivery. The percentage of emergency caesarean delivery was 16.6, 22.2, 23.0, and 33.3%, in cases

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Table 5 Plasma glucose values in different samples (mean [standard deviation]) in gestational diabetes mellitus by O'Sullivan's and World Health Organization criteria at 24–28 weeks of pregnancy.

Sample	O'Sullivan's				WHO	
	+ve (*n*=25)	% Above cut-off	−ve (*n*=698)	% Above cut-off	+ve (*n*=35)	% Above cut-off
Fasting	79–136 (102 [14.1])	48	45–128 (81.5 [11.6])	2.5	68–132 (96 [16])	5.7
1 hr	147–307 (208.6 [32.3])	84	61–226 (123 [28.9])	2.3		
2 hr	113–213 (181 [22.2])	80	45–212 (110.5 [22.3])	1.2	115–175 (148.5 [1])	94.3
3 hr	50–192 (129 [34.8])	52	44–150 (94.7 [18.6])	0.6		

WHO: World Health Organization.

Table 6 Association between modes of delivery and presence of gestational diabetes mellitus by number of different criteria.

GDM by criteria	Delivery *n* (%)					
	Emergency caesarean	Post-LSCS caesarean	Other	Abnormal	Normal	Total
0	35 (13.1)	20 (7.5)	14 (5.2)	69 (25.7)	199 (74.3)	268 (92.1)
1	3 (20.0)	1 (6.6)	1 (6.6)	5 (33.3)	10 (66.7)	15 (5.1)
2	2 (25.0)	1 (12.5)	0	3 (37.5)	5 (62.5)	8 (2.8)
Total	40 (13.7)	22 (7.6)	15 (5.2)	77 (26.5)	214 (73.5)	291 (100)

GDM: gestational diabetes mellitus, LSCS: lower segment caesarean section.
χ^2=0.93, df=2, *P*=0.63, not significant, contingency coefficient=0.056 (poor association).

diagnosed GDM at 24–28 weeks by WHO, modified, Carpenter's and O'Sullivan's criteria, respectively (Table 8). However, the number of GDM by O'Sullivan's criteria is small (*n*=6) and there are other indications for emergency LSCS. Relative risk of abnormal delivery in GDM compared to nonGDM was 1.77, 1.39, 1.17, and 1.93, diagnosed by modified, WHO, Carpenter's and O'Sullivan's criteria, respectively (Table 3). However, data being limited no significant conclusions can be drawn.

The incidence of isolated hyperglycaemia was highest in one-hour sample (58.6%), similar findings have also been reported by Retnakaran et al who found that among 39 cases of isolated hyperglycaemia of pregnancy, 15 had values above cut-off for plasma glucose at one-hour, postglucose load.[15] They observed that individuals with one-hour IGT were metabolic phenotype of GDM while those with two-hours/three-hours isolated hyperglycaemia were metabolic phenotype of normal glucose tolerance (NGT).

We analysed whether glycated haemoglobin can be useful in the diagnosis of GDM. Amongst subjects (*n*=236), with normal HPLC profile for glycated haemoglobin, five patients of GDM were diagnosed with O'Sullivan's criteria. We found that none of the patient had glycated haemoglobin of >6.0%, a cut-off used by Radder et al[16] for the diagnosis of GDM. Therefore, the incidence of GDM is not only small but the severity of GDM is also much less, as the rise in glycated haemoglobin >6.0% was not observed.

We grouped the insulin values on the basis of percentiles. Insulin levels both fasting and two-hours postprandial and pregnancy outcome were studied. We found no significant association between them, the *P* value was >0.05. Abnormal deliveries were marginally higher in women with higher

Table 7 Comparison of parameters for assessing diagnostic utility of a test for diagnosis of gestational diabetes mellitus with O'Sullivan's criteria as gold standard* (*n*=723).

Criteria	Sensitivity	Specificity	PPV	NPV
WHO criteria	0.20	0.96	0.14	0.97
Modified criteria (fasting (100 mg/dL) and two-hours post-glucose ≥140 mg/dL)	0.08	0.99	0.18	0.97
Carpenter and Coustan's criteria	1.0	0.97	0.54	1.0

NPV: negative predictive value, PPV: positive predictive value, WHO: World Health Organization.
*Gestational diabetes mellitus +ve with O'Sullivan's criteria (*n*=25).

two-hours postglucose load insulin levels (Table 4). This may have clinical significance.

In our study none of the infant had neonatal convulsions and neural tube defects. Only one case of macrosomia (4.003 Kg) was present in nonGDM group. Two still born babies and two cases of IUGR to nonGDM mothers were recorded. The classical complications described to be present in GDM were absent in our study, even in cases diagnosed by O'Sullivan's criteria.

CONCLUSION

To define a cut-off value for GDM in Indian women above which maternal and/or neonatal complications start, a larger

Table 8 Presence of gestational diabetes mellitus at 24–28 weeks by various criteria and pregnancy outcome ($n = 291$).

GDM Criteria	+ve (n)	Emergency caesarean	Post-LSCS caesarean	Other	Abnormal	Normal
O'Sullivan's	6	2 (33.3)	1 (16.7)	0 (0)	3 (50.0)	3 (50.0)
Carpenter's	13	3 (23.0)	1 (7.6)	0 (0)	4 (30.8)	9 (69.2)
WHO	12	2 (16.6)	1 (8.3)	1 (8.3)	4 (33.3)	8 (66.7)
Modified	2	1 (50.0)	–	1 (50.0)	2 (100.0)	0 (0.0)

GDM: gestational diabetes mellitus, LSCS: lower segment caesarean section, WHO: World Health Organization.

population with longer follow-up and higher number of high-risk group individuals need to be studied. This study highlights the futility of screening pregnant women of <25 years of age for GDM in absence of known risk factors. As the plasma glucose abnormalities observed in the present study are more frequent in 100 g one-hour and two-hours samples postglucose load; further study could be carried out to compare O'Sullivan's criteria and ADA-2011 criteria[17] as it requires collection of three samples at zero, one, and two hours, 75 g postglucose load.

Intellectual Contributions of Authors

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CONFLICTS OF INTEREST

This study has been financed by the research grants from the office of the DGAFMS.

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